FEB 1 3 2002

510(K) SUMMARY

Omnia X/XS Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
Siemens Medical Solutions USA, Inc., Ultrasound Group
22010 S.E. 51st Street
Issaquah, WA 98029

Contact Person:
Judi Hoffman
Regulatory Affairs

Phone: (425) 557-1229
FAX: (425) 391-9198

Date Prepared:
December 19, 2001

2. **Proprietary Name:**
Omnia X/XS Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. **Predicate Device:**
K945773, 8/7/95, cleared as the Versa, marketed as the SONOLINE Versa/Versa Pro/Versa Plus/ Omnia with subsequent modifications.
K945072, 11/21/95, cleared as Q4000, marketed as SONOLINE Elegra/Elegra Advances/Antares with subsequent modifications.

4. **Device Description:**
The Omnia X/XS is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, or 3D imaging, on a CRT display.

The Omnia X/XS, has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The Omnia X/XS ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

The Omnia X/XS is substantially equivalent to the SONOLINE Versa, cleared via K945773, and modified via K962142, K962882, and K992046; and some features of the SONOLINE Elegra, cleared via K945072, and modified via K961833, K981626, K980557, K981528 and K001400. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

Siemens Medical Solutions, USA
% Mr. Mark Job
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K020353
Trade Name: SONOLINE Omnia X/XS Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYN and IYO
Dated: February 1, 2002
Received: February 4, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE Omnia X/XS Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number
C5-2 Convex Array
C6-2 Convex Array
C8-5 Convex Array
5.0C50+ Convex Array

C6-3 3D Mechanically Driven 3D Convex Array
EV9-4 Convex Array Endovaginal
Endo-VII Mechanical Sector Endovaginal
Endo-V 3D Mechanical Sector Endovaginal
EC9-4 Convex Array Endovaginal
5.0L45 Linear Array
7.5L70 Linear Array
LB5-2 Linear Array
L10-5 Linear Array
VF13-5 Linear Array
VF13-5SP Linear Array
7.5L50I Linear Array
7.5L50Q Linear Array
LAP8-4 Laparoscopic
P4-2 Phased Sector Array
5.0P10 Phased Sector Array
MPT7-4 Phased Sector Array TEE
CW2 CWD
CW5 CWD

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Attachment 4

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SONOLINE Omnia X/XS (Versa Family) Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		P	P	P	P	P	P		BMDC (P)	P	N
Abdominal		P	P	P	P	P	P		BMDC (P)	P	N
Intraoperative Abdominal		P	P	P		P	P		BMDC (P)		N
Intraoperative Neurological		P	P	P		P	P		BMDC (P)		N
Pediatric		P	P	P	P	P	P		BMDC (P)	P	N
Small Organ (Specify)**		P	P	P	P	P	P		BMDC (P)	P	N
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)		N
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	P	
Cardiac		P	P	P	P	P	P		BMDC (P)	P	
Transesophageal		P	P	P		P	P		BMDC (P)	N	N
Transrectal		P	P	P		P	P		BMDC (P)	N	N
Transvaginal		P	P	P		P	P		BMDC (P)	N	N
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	P	N
Laparoscopic		P	P	P		P	P		BMDC (P)		N
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC (P)	P	N
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC (P)	N	N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Jayne

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: C5-2 Convex Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		E	E	E		E	E		BMDC (E)	E	
Abdominal		E	E	E		E	E		BMDC (E)	E	
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E		E	E		BMDC (E)	E	
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E		E	E		BMDC (E)	E	
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-2** Convex Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: C8-5 Convex Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		E	E	E		E	E		BMDC (E)		N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E		E	E		BMDC (E)		N
Small Organ (Specify)**		N	N	N		N	N		BMDC (N)		N
Neonatal Cephalic		E	E	E		E	E		BMDC (E)		N
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)		N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0C50+** Convex Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		P	P	P	P	P	P		BMDC (P)		N
Abdominal		P	P	P	P	P	P		BMDC (P)		N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E	E	E	E		BMDC (E)		N
Small Organ (Specify)**		E	E	E	E	E	E		BMDC (E)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		BMDC (P)		N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-3 3D** Mechanically driven 3D Convex Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)		N
Abdominal		N	N	N		N	N		BMDC (N)		N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)		N
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seyman

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and **Radiological Devices**
510(k) Number K020552

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV9-4** Convex Array Endovaginal Transducer
for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal		N	N	N		N	N		BMDC (N)	N	N
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Endo-VII** Mechanical Sector Endovaginal Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N						BM (N)		N
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic		N	N						BM (N)		N
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal		N	N						BM (N)		N
Transvaginal		N	N						BM (N)		N
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Additional Comments: _____

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Endo-V 3D** Mechanical Sector Endovaginal Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N						BM (N)		N
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal		N	N						BM (N)		N
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013053

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: EC9-4 Convex Array Endovaginal Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal		N	N	N		N	N		BMDC (N)	N	N
Transvaginal		N	N	N		N	N		BMDC (N)	N	N
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David C. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0L45** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)**		P	P	P	P	P	P		BMDC (P)	P	N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	P	N
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC (P)	P	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L70** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)		N
Small Organ (Specify)**		P	P	P		P	P		BMDC (P)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)		N
Musculo-skeletal Superficial		E	E	E		E	E		BMDC (E)		N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **LB5-2** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		E	E	E		E	E		BMDC (E)		
Abdominal		E	E	E		E	E		BMDC (E)		
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legnon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **L10-5** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial		N	N	N		N	N		BMDC (N)	N	N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)		N
Small Organ (Specify)**		E	E	E	E	E	E		BMDC (E)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E	E	E	E		BMDC (E)		N
Laparoscopic											
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC (E)		N
Musculo-skeletal Superficial		E	E	E	E	E	E		BMDC (E)		N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5SP** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		N	N	N		N	N		BMDC (N)		N
Intraoperative Neurological		N	N	N		N	N		BMDC (N)		N
Pediatric		N	N	N		N	N		BMDC (N)		N
Small Organ (Specify)**		N	N	N		N	N		BMDC (N)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)		N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)		N
Musculo-skeletal Superficial		N	N	N		N	N		BMDC (N)		N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lepore

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and **Radiological Devices**
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L50I** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		E	E	E		E	E		BMDC (E)		N
Intraoperative Abdominal		P	P	P		P	P		BMDC (P)		N
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E		E	E		BMDC (E)		N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)		N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Krysman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L50Q** Linear Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		P	P	P		P	P		BMDC (P)		N
Intraoperative Abdominal		E	E	E		E	E		BMDC (E)		N
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E		E	E		BMDC (E)		N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)		N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **LAP8-4** Laparoscopic Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		P	P	P		P	P		BMDC (P)		N
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic		P	P	P		P	P		BMDC (P)		N
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Sector Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal		E	E	E	E	E	E		BMDC (E)	E	
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic		E	E	E	E	E	E		BMDC (E)	E	
Cardiac		E	E	E	E	E	E		BMDC (E)	E	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legramm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020559

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0P10** Phased Sector Array Transducer for use with SONOLINE Omnia X/XS

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal		P	P	P	P	P	P		BMDC (P)		
Abdominal		P	P	P	P	P	P		BMDC (P)		
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)		
Small Organ (Specify)											
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)		
Adult Cephalic											
Cardiac		P	P	P	P	P	P		BMDC (P)		
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Hegyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020353

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **MPT7-4** Phased Sector Array TEE Transducer for use with SONOLINE Omnia X/XS

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal		N	N	N		N	N		BMDC (N)	N	N
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030353